# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	) ) )	MDL No. 02419 Docket No. 1:13-md-2419-RWZ
This document relates to:	) )	
All of the cases against the Box Hill Defendants	) ) )	

# THE BOX HILL DEFENDANTS' FIRST SET OF INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS AND REQUESTS FOR ADMISSION PROPOUNDED TO GLENN CHIN

Come the Defendants Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (collectively "Box Hill Defendants"), pursuant to Rules 26, 33, and 34 of the Federal rules of Civil Procedure and the Local Rules for the District of Massachusetts, and propound the following Interrogatories, Requests for Production of Documents and Requests for Admission to Glenn Chin.

Each of the following Interrogatories shall be answered under oath, in writing, separately, to the fullest possible detail, and in accordance with the definitions and instructions set forth below. The answers shall be signed by the person making them, and a copy of the answers, together with objections, if any, shall be served within thirty (30) days after the service date of these Interrogatories.

You are under a duty to seasonably supplement your response with respect to any Interrogatory directly addressed to the identity and location of persons having knowledge of discoverable matters. You are under a duty to amend a prior response if you obtain information on the basis of which you know that the response was incorrect when made, or that the response, though correctly made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

# **DEFINITIONS**

1. As used in this document, the term "person(s)" and "individual(s)" mean any natural individual in any capacity whatsoever or any entity or organization, including divisions, departments, and other units therein, and shall include, but not be limited to, a public or private corporation, partnership, joint venture, voluntary or unincorporated association, organization, proprietorship, trust, estate, governmental agency, commission, bureau, or department.

- 2. As used in this document, the term "document" means any medium upon which intelligence or information can be recorded or retrieved, and includes without limitation, the original and each copy, regardless of origin and location, of any book, pamphlet, periodical, letter, memorandum (including any memorandum or report of a meeting or conversation), invoice, bill, order form, receipt, financial statement, accounting entry, diary, calendar, telex, telegram, cable, report, record, contract, agreement, study, handwritten note, draft, working paper, chart, paper, print, laboratory record, drawing or sketch, graph, index, lists, tape, photograph, microfilm, data processing card, or any other written recorded, transcribed, punched, taped, filmed, or graphic matter, however produced or reproduced, which is in your possession, custody or control, or which was, but is no longer, in your possession, custody, or control.
- 3. As used in this document, the terms "identification," "identify," or "identity," when used in reference to a natural individual, require you to state his or her full name and residential and business address. Use of the term "document" in connection with the Interrogatories requires you to state the number of pages and the nature of the documents, its title, its date, the name or names of its authors, and recipients and its present location and custodian.
- 4. "You" and "your" refers to Glenn Chin and each of its present and former agents, representatives and employees, attorneys and accountants, and each person acting or purporting to act on its behalf.
- 5. "Communication" means any oral or written utterance, notification, or statement of any nature whatsoever, by and to whomsoever made, including, but not limited to, correspondence, conversation, dialogue, discussions, interviews, consultants, and any other understanding between or among two or more persons.

### INSTRUCTIONS

1. With respect to each Interrogatory, in addition to answering the question, you are to identify all documents that support, refer to, or evidence the subject matter of each Interrogatory and your answer thereto.

If any or all identified documents are no longer in your possession, custody, or control because of destruction, loss or any other reason, then you must do the following with respect to each and every document:

- A. Describe the nature of the document.
- B. State the date of the document;
- C. Identify the persons who sent and received the original and the copy of the document;
- D. State in as much detail as possible the contents of the documents; and

E. State the manner and date of disposition of the document.

If you contend that you are entitled to withhold from production any or all documents identified herein on the basis of attorney-client privilege, the work-product doctrine, or any other ground, then do the following with respect to each and every document.

- A. Describe the nature of the document;
- B. State the date of the document;
- C. Identify the persons who sent and received the original and a copy of the document;
- D. State the subject matter of the document; and,
- E. State the basis upon which you contend you are entitled to withhold the document from production.
- 2. All documents produced should be organized and labeled to correspond to the specific Request in response to which they are being made available or should be produced as they are kept in the usual course of business.
- 3. The terms "and," "or," and "and/or" should be construed either disjunctively or conjunctively so as to bring within the scope of these Interrogatories and Requests and information that might otherwise be construed as outside their scope.
- 4. The term "any" should be construed to include the word "all," and "all" should be construed to include "and."
- 5. The present tense should be construed to include the past tense, and the past tense should be construed to include the present tense.
- 6. The singular should be construed to include the plural, and the plural should be construed to include the singular.
- 7. The terms "he" and "his" should be construed to include the words "she" and "her" or "hers," respectively and vice versa.
- 8. "Relating to," when referring to a document shall mean mentioning, describing, connected to or with, or discussing the stated subject matter.

# INTERROGATORIES

On March 19, 2015, the Saint Thomas Entities sent their First Set of Interrogatories, Requests for Production and Requests for Admission to Glenn Chin. In order to minimize the impact of discovery on Glenn Chin, these Box Hill Defendants hereby adopt and incorporate, as if stated fully herein, Interrogatories 1-6 from the Saint Thomas Entities' First Set of Interrogatories to Liberty. On March 31, 2015, the Tennessee Clinic Defendants sent their First Set of Interrogatories, Requests for Production, and Requests for Admissions to Glenn Chin. In order to minimize the impact of discovery on Glenn Chin, these Box Hill Defendants hereby adopt and incorporate, as if stated fully herein, Interrogatories 7-20 from the Tennessee Clinic Defendants First Set of Interrogatories. [Dkt.1742]. To the extent that any of those adopted Interrogatories request information pertaining to the Tennessee Clinic Defendants or the Saint Thomas Entities, please consider it a request for information related to the Box Hill Defendants. The "new" Interrogatories begin at Number 21.

1-6. [The Box Hill Defendants adopt and incorporate, as if stated fully herein, Interrogatories 1-6 from the Saint Thomas Entities; First Set of Interrogatories to Glenn Chin.]

ANSWER:

7-20. [The Box Hill Defendants adopt and incorporate, as if fully state herein, Interrogatories 7-20 from the *Tennessee Clinic Defendants' First Set of Interrogatories to Glenn Chin.*]

ANSWER:

21. Describe all communication you had with the Box Hill Defendants, their employees or agents, including Ritu Bhambhani, M.D. about the contaminated NECC MPA at issue.

ANSWER:

# **REQUESTS FOR PRODUCTION**

On March 19, 2015, the Saint Thomas Entities sent their First Set of Interrogatories, Requests for Production and Requests for Admission to Glenn Chin. In order to minimize the impact of discovery on Glenn Chin, these Box Hill Defendants hereby adopt and incorporate, as if stated fully herein, Requests for Production 1-39 from the Saint Thomas Entities' First Set of Requests for Production to Liberty. The "new" requests begin at Number 40.

1-39. [The Box Hill Defendants adopt and incorporate, as if stated fully herein, Requests for Production 1-39 from the Saint Thomas Entities' First Set of Requests for Production to Liberty.]

### RESPONSE:

40. Produce all correspondence between you and any of the Box Hill Defendants, their employees, agents or representatives.

# RESPONSE:

41. Produce all correspondence and documents referring or relating to the Box Hill Defendants' purchase of MPA from NECC for a 5-year period, including and prior to 2012.

# RESPONSE:

42. Produce all documents produced by the government to you during any civil, criminal, or administration proceedings related to NECC's contaminated MPA.

# RESPONSE:

43. Produce all policies, procedures, guidelines, instructions and training documents referring or relating to the compounding of MPA at the NECC facility.

### **RESPONSE:**

44. Produce all documents referring or relating to NECC or Ameridose sending sufficient samples, by size or volume, to comply with USP 71 to ARL or any other testing laboratory.

45. Produce all documents referring or relating to any sterility, potency, endotoxin, or fungal testing that you received from ARL or any other laboratory related to MPA compounded by NECC or Ameridose in 2011 and 2012.

### RESPONSE:

46. Produce all correspondence and documents referring or relating to fungal blooms or growth in or near NECC's cleanrooms.

### RESPONSE:

47. Produce all documents referring or relating to any complaints that NECC or Ameridose received related to the sterility or safety of their products, including but not limited to, complaints by customers, current or former employees, or state or federal government agencies.

# **RESPONSE:**

48. Produce all documents referring or relating to any complaints NECC or Ameridose received related to their compliance with state or federal laws and regulations, including but not limited to, complaints by customers, current or former employees, or state or federal government agencies.

### RESPONSE:

49. Produce all correspondence and documents referring or relating to NECC's response to the meningitis outbreak, including, but not limited to, steps NECC took to prepare for any inspections of its facility.

### **RESPONSE:**

50. Produce all training and instructional material for sales staff at NECC or MSM.

# **REQUESTS FOR ADMISSION**

On March 19, 2015, the Saint Thomas Entities sent their First Set of Interrogatories, Requests for Production and Requests for Admission to Glenn Chin. In order to minimize the impact of discovery on Glenn Chin, these Box Hill Defendants hereby adopt and incorporate, as if stated fully herein, Requests for Admission 1-17 from the Saint Thomas Entities' First Set of Requests for Admission to Liberty. The "new" requests being at Number 18.

1-17. [The Box Hill Defendants adopt and incorporate, as if stated fully herein, Requests for Admission 1-17 from the *Saint Thomas Entities' First Set of Requests for Admission* to Glenn Chin.]

# RESPONSE:

18. Admit that you compounded the MPA lots numbered 052122012@68, 06292012@26 and 08102012@51 (collectively "Contaminated Lots").

#### RESPONSE:

19. Admit that you supervised the compounding of MPA lots numbered 052122012@68, 06292012@26 and 08102012@51 (collectively "Contaminated Lots").

# RESPONSE:

20. Admit that as a supervising pharmacist, you owed a duty to the Plaintiffs to ensure that NECC's cleanroom was sterile prior to compounding any medications, including MPA in 2012.

#### RESPONSE:

21. Admit that as a supervising pharmacist, you owed a duty to the Plaintiffs to ensure that the MPA you compounded was sterile before you distributed it to customers.

# RESPONSE:

21. Admit that, had any of the Box Hill Defendants asked for a copy of NECC's license prior to and including 2012, you would have provided a valid and up-to-date Massachusetts pharmacy license and a valid and up-to-date license with the Maryland Board of Pharmacy.

# **RESPONSE:**

22. Admit that NECC represented to its customers, including the Box Hill Defendants, that it met or exceeded USP 797 standards.

# RESPONSE:

23. Admit that NECC represented to its customers, including the Box Hill Defendants, that its products, including MPA, were safe and sterile.

### RESPONSE:

24. Admit that the Massachusetts Board of Pharmacy ("Mass BoP") inspected NECC on or about May 24, 2011.

### RESPONSE:

25. Admit that as a result of its inspection on or about May 24, 2011 the Mass BoP issued an inspection report documenting its findings.

#### RESPONSE:

26. Admit that NECC failed to submit a copy of the Mass. BoP's May 24, 2011 inspection report to the Maryland Board.

# RESPONSE:

27. Admit that the documents attached as Exhibit B are NECC's Logged Formula Worksheets for the Contaminated Lots.

### RESPONSE:

28. Admit that in each Logged Formula Worksheet in Exhibit B, the pharmacist referred to as "GC" is Glenn Chin.

29. Admit that the Logged Formula Worksheet for lot 06292012@26, attached as Exhibit B, states that the MPA was autoclaved for twenty (20) minutes at 121 C. and 15-PSI.

### RESPONSE:

30. Admit that NECC's Standard Operating Procedures required that the MPA be autoclaved for fifteen (15) minutes at 121 C. and 15 PSI.

### RESPONSE:

31. Admit that the Logged Formula Worksheets in Exhibit B state that Joseph P. Connolly was the technician for MPA lots 052122012@68 and 06292012@26.

### RESPONSE:

32. Admit that Exhibit C is NECC's General Overview of Policies & Procedures for Compounding Sterile Products.

### RESPONSE:

33. Admit that Exhibit C states, in part:

# C. Personnel

a. All sterile compounding is performed by properly trained and validated pharmacists (no technicians).

# RESPONSE:

34. Admit that NECC violated its own standard operating procedures by permitting Joseph Connolly (a technician) to compound two of the three contaminated lots.

# RESPONSE:

35. Admit that you owed a duty to NECC's customers to ensure that NECC's MPA was sterile prior to distributing it.

36. Admit that NECC distributed some of the MPA from the Contaminated Lots prior to receiving final sterility, fungal, endotoxin, or potency testing results from its outside laboratory.

### RESPONSE:

37. Admit that the documents attached as Exhibit D are reports from analytical Research Laboratories ("ARL") related to the sterility and endotoxin testing ARL performed on NECC's MPA from the Contaminated Lots.

# RESPONSE:

38. Admit that NECC submitted only two 5 mL vials of MPA from each of the Contaminated Lots to ARL for testing.

#### RESPONSE:

39. Admit that USP standards for sterility testing required a larger sample size than two 5 mL vials per lot of MPA.

#### **RESPONSE:**

40. Admit that USP 797 requires an ISO 5 space for stoppering vials of MPA.

# RESPONSE:

41. Admit that NECC stoppered the Contaminated Lots in an ISO 7space.

# RESPONSE:

42. Admit that the documents attached as Exhibit E are true and accurate copes of emails you received from Barry Cadden in the normal course of NECC's business.

43. Admit that in the email you received from Barry Cadden on Wednesday, August 10, attached as Exhibit E, Barry Cadden stated, "I am told that the lots for some drugs almost never coincide with the available test data."

#### RESPONSE:

44. Admit that in the email you received from Barry Cadden on Wednesday, August 10, attached as Exhibit E, Barry Cadden stated, "I was told that we are only testing rarely and dispensing many untested lots."

# RESPONSE:

45. Admit that Exhibit F is a true and accurate copy of an email you sent to Barry Cadden on Monday, December 19, 2011.

### RESPONSE:

46. Admit that the email in Exhibit F was sent in the normal course of NECC's business.

### RESPONSE:

47. Admit that in the email attached as Exhibit F, you indicated that you were using "MTX" that had expired in 2007 in NECC's injectable products in 2011.

# **RESPONSE:**

Respectfully submitted,

/s/ Gregory K. Kirby
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# **CERTIFICATE OF SERVICE**

This is to certify that a copy of the foregoing Interrogatories, Requests for Production of Documents, and Requests for Admission has been served on the below listed counsel for Glenn Chin on July 30, 2015 via U.S. Mail, postage pre-paid. Thereafter, a copy was filed on the Court's CM/ECF system to ensure that all interested parties can access it.

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/s/ Gregory K. Kirby
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